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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,372	12/21/2001	Roger A. Sabbadini	078853-0302	3592

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/029,372

Applicant(s)

SABBADINI, ROGER A.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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1. Claims 1-20 are pending in this application.
2. The rejection of claims 1 and 5-17 under 35 USC 112, second, paragraph statute is withdrawn in view of the claim amendment filed May 23, 2003.
3. The rejection of claims 1-20 under 35 USC 103(a) as unpatentable over Marangos (US 5,677,288) in view of Webster's Dictionary (1990) has been maintained for reasons of record.
4. Applicant's arguments filed May 23, 2003 have been fully considered but they are not persuasive.

The examiner disagrees with applicant's argument at page 6 of the amendment filed May 23, 2003, stating that "Marangos completely fails to disclose altering the activity or concentration of such an enzyme in the treatment of cardiovascular or cerebrovascular disease.", for the reasons of record and given below. First, Marangos discloses a method relating to pharmacology and neurology and involves drugs that can prevent or reduce nerve cell death or damage due to conditions such as stroke, drowning, cardiac arrest, or various injuries or diseases. Secondly, Marangos discloses that the method involves administering an aminoglycoside and specifically discloses administering gentamicin. Thirdly, Marangos discloses administering aminoglycosides during in vitro and in vivo testing of mammalian neuronal tissue from mammals having a variety of neuronal conditions. Fourth, Marangos discloses ischemia was a condition treated with the aminoglycoside. Fifth, it was well known in this art at the time this

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invention was made that many of the Marangos treatment methods were encompassed by the art recognized definitions for cardiovascular and cardiovascular. Sixth, the 35 USC 103(a) statute does not require the Marangos reference to use the exact words set forth in the instant claim limitations in order to render the present invention obvious in view of the Webster's Dictionary definitions. Moreover, the examiner disagrees with applicant's assertion that Marangos disclosure does not render obvious the instant invention because "Marangos discloses the suppression of the flow of calcium ions into neurons through presynaptic N-type calcium channels (Col. 8, line 59- Col. 9, line 34)" because Marangos can disclose, suggest or claim other inventions as well as limitations claimed in the instant invention as stated above.

The examiner has carefully considered applicants statement that "Webster's dictionary simply provides a definition of sphingosine, which includes the disclosure that sphingosine is present in nervous tissue and cell membranes." However, regarding the sphingosine limitation in the instant invention, Webster defines "shpingosine" as "a long-chain unsaturated amino $C^{18}H_{37}O_2N$ found esp. in nervous tissue and cell membranes" which sufficiently described the presence of sphingosine in nervous tissue and cell membranes before this invention was made.

Applicants have also argued "But even Marangos and Webster's dictionary together completely fail to disclose altering the activity or concentration of an enzyme with the recited properties in the treatment of cardiovascular or cerebrovascular disease." However, with respect to the recited properties, Marangos discloses administering one of the same agents described in the instant claims which "alters the

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activity of concentration of an enzyme, wherein said enzyme catalyzes a reaction that produces or degrades a sphingolipid or a sphingolipid metabolite”.

The examiner has considered applicant's contentions that “Webster's 10th edition dictionary defines an enzyme as “a protein that catalyze specific biochemical reactions” (p. 388), while an ion channel (such as the N-type calcium channel of Marangos) is defined as “a passage created in a selectively permeable membrane by a conformational change in membrane proteins” (p. 191). Therefore, the references themselves make clear that an ion channel is not an enzyme.” However, it is noted that Marangos does not have to implicitly state or describe an enzyme nor an ion and/or the specific properties. Rather, Marangos discloses the invention claimed except for addressing the enzymatic activity of aminoglycoside on sphingosine or sphingolipid metabolite with was provided Webster's dictionary definition of “sphingosine” that sufficiently described the presence of sphingosine in nervous tissue and cell membranes prior to the conception of the present invention.

For reasons give above, Marangos in view of Webster's Dictionary renders the instantly claimed invention obvious.

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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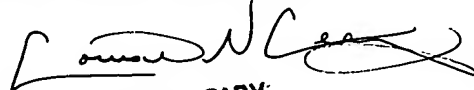
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

August 25, 2003